

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Mariagrazia
Pizza, Maria Rita Fontana, Valentina
Giannelli and Rino Rappuoli

COPY

Serial No.: Not Yet Assigned

Group Art Unit: Not Yet Assigned

Filing Date: March 28, 2001

Examiner: Not Yet Assigned

For: IMMUNOGENIC DETOXIFIED MUTANTS OF CHOLERA TOXIN

EXPRESS MAIL LABEL NO: EL650 273 365US
DATE OF DEPOSIT: March 28, 2001

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

DECLARATION OF DOREEN YATKO TRUJILLO

1. I am an attorney admitted to practice law in the States of Texas and Pennsylvania, and am registered before the United States Patent and Trademark Office, Registration No. 35,719.
2. I am an attorney of record in the parent of present patent application.
3. The "Preliminary Amendment" submitted herewith includes an amendment to incorporate a statement, and figure to which the statement refers, from WO 93/13202 incorporated by reference thereto in the present application as filed.
4. The statement is presumed to be essential, as is the figure to which it refers.
5. On page 5, line 33, through page 6, line 6, of the above-identified application as filed, the disclosure of immunogenic detoxified proteins in WO 93/13202 comprising mutations at one or more select amino acid positions in the amino acid sequence of subunit A of cholera toxin (CT-A) and subunit A of heat labile toxin A (LT-A) is described.

6. On page 7, lines 1-3, of WO 93/13202, it is reported that the amino acid positions referred to therein correspond to positions in CT-A. Figure 1 is referenced. Figure 1 of WO 93/13202 includes a comparison of CT-A and various LT-A sequences.

7. The description of Figure 1 on page 11, lines 20-27, of WO 93/13202, indicates that the symbol “.” denotes an absent amino acid and the symbol “-” indicates an amino acid in the sequences of LT1 and LT2 that is identical to the corresponding amino acid in CT.

8. The amendatory material consists of information from lines 1-3 on page 7, and lines 20-27 on page 11, of WO 93/13202.

9. The amendatory material, thus, consists of the same material incorporated by reference.

10. I hereby declare that all statements made herein are of my own knowledge true and statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

March 28, 2001
Date

Doreen Yatko Trujillo
Doreen Yatko Trujillo
Registration No. 35,719

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Pizza et al.

Serial No.: 09/819,917

Group No.: Not Yet Assigned

Filing Date: March 28, 2001

Examiner: Not Yet Assigned

For: IMMUNOGENIC DETOXIFIED MUTANTS OF CHOLERA TOXIN

I, Doreen Yatko Trujillo, Registration No. 35,719 certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Box DSD, Assistant Commissioner for Patents, Washington, D.C. 20231.

On October 29, 2001
Doreen Yatko Trujillo
Doreen Yatko Trujillo, Reg. No. 35,719

BOX DSD

Assistant Commissioner for Patents
Washington, D.C. 20231

STATEMENT UNDER 37 C.F.R. §3.73(b)

Chiron S.p.A., a corporation, states that it is:

1. the assignee of the entire right, title, and interest; or
2. an assignee of an undivided part interest

in the patent application/patent identified above by virtue of either:

- A. An assignment from the inventor(s) of the patent application/patent identified above.
 1. The assignment was recorded in the Patent and Trademark Office at Reel 011301, Frame(s) 0630.
 2. The assignment has not yet been recorded. A copy of the assignment is attached.

OR

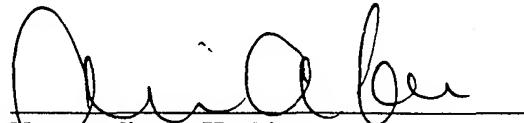
- B. A chain of title from the inventor(s), of the patent application/patent identified above, to the current assignee as shown below:

- i. From: @@ To: @@ The document was recorded in the Patent and Trademark Office at Reel @@, Frame(s) @@, or for which a copy thereof is attached.
- ii. From: @@ To: @@ The document was recorded in the Patent and Trademark Office at Reel @@, Frame(s) @@, or for which a copy thereof is attached.
- iii. From: @@ To: @@ The document was recorded in the Patent and Trademark Office at Reel @@, Frame(s) @@, or for which a copy thereof is attached.

Additional documents in the chain of title are listed on a supplemental sheet.
 Copies of assignments or other documents in the chain of title are attached.

The undersigned (whose title is supplied below) is empowered to act on behalf of the assignee, **Chiron S.p.A.**

Date: 14 August 2001



Name: Alisa A. Harbin
Title: Vice President and Associate Chief
Patent Counsel
Corporation: Chiron Corporation

DOCKET NO. CHIR-0312

PATENT

[COMMENT1]

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: **Mariagrazia Pizza,
Maria Rita Fontana, Valentina Giannelli and
Rino Rappuoli**

Group Art Unit: Not Yet
Assigned

For: **IMMUNOGENIC DETOXIFIED
MUTANTS OF CHOLERA TOXIN**

Examiner: Not Yet Assigned

DECLARATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name; and

I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a

Utility Patent Design Patent

is sought on the invention, whose title appears above, the specification of which:

is attached hereto.
 was filed on March 28, 2001 as Serial No. 09/819,917.
 said application having been amended on

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to be material to the patentability of this application in accordance with 37 CFR § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a-d) of any **foreign application(s)** for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of any application on which priority is claimed:

Priority	Country	Serial Number	Date Filed
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Claimed
(If X'd)

United Kingdom9513371.6June 30, 1995ItalyMI 91 A 03513December 31, 1991

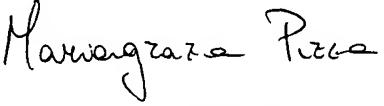
I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to be material to patentability as defined in 37 CFR § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

Serial Number	Date Filed	Patented/Pending/Abandoned
<u>08/981,208</u>	<u>December 22, 1997</u>	<u>Pending</u>
<u>08/823,120</u>	<u>March 25, 1997</u>	<u>Now, U.S. Pat. No. 6,149,919</u>
<u>08/256,003</u>	<u>November 11, 1994</u>	<u>Abandoned</u>

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Serial Number	Date Filed
_____	_____
_____	_____

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Name: Mariagrazia Pizza	 Signature
Mailing Address: Via Vittorio Emanuele, 33 53100 Siena Italy	Date of Signature: 10/05/01
City/State of Actual Residence: 53100 Siena Italy	Citizenship: Italian

Name: Maria Rita Fontana	 Signature
Mailing Address: Via del Colle, 19 53100 Siena Italy	Date of Signature: 10/05/01
City/State of Actual Residence: 53100 Siena Italy	Citizenship: Italian

Name: Valentina Giannelli	
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Name: Valentina Giannelli	
Mailing Address: Via Corsano Grotti, 26 53010 Ville di Corsano Monteroni d'Arbia (SI) Italy	<i>Giannelli</i> <i>Monteroni d'Arbia</i>
City/State of Actual Residence: Monteroni d'Arbia (SI) Italy	

Name: Rino Rappuoli	 Signature
Mailing Address: Via delle Rocche, 1 Vagliagli 53019 Castelnuovo Berardenga (SI) Italy	
City/State of Actual Residence: 53019 Castelnuovo Berardenga (SI) Italy	Date of Signature: 10/05/04
	Citizenship: Italian

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of: Pizza et al.**Serial No.: 09/819,917****Group No.: Not Yet Assigned****Filing Date: March 28, 2001****Examiner: Not Yet Assigned****For: IMMUNOGENIC DETOXIFIED MUTANTS OF CHOLERA TOXIN**

I, Doreen Yatko Trujillo, Registration No. 35,719 certify that this correspondence is being deposited with the U.S. Postal Service as First Class mail in an envelope addressed to Box DSD, Assistant Commissioner for Patents, Washington, D.C. 20231.

On October 29, 2001
Doreen Yatko Trujillo
Doreen Yatko Trujillo Reg. No. 35,719

BOX DSD

Assistant Commissioner for Patents
Washington, D.C. 20231

POWER OF ATTORNEY

Pursuant to 37 C.F.R. § 1.36, Chiron S.p.A., the Assignee of the above-identified application, hereby appoints the following attorneys and agents to prosecute this application and to transact all business in the Patent and Trademark Office in connection therewith.

Robert P. Blackburn	Registration No. 30,447	Joseph H. Guth	Registration No. 31,261
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David P. Lentini	Registration No. 33,944	Kimberlin L. Morley	Registration No. 35,391
Lisa E. Alexander	Registration No. 41,576	Anne S. Dollard	Registration No. 43,935

of CHIRON CORPORATION, 4560 Horton Street, Emeryville, CA 94608-2916, and

Richard E. Kurtz	Registration No. 19,263	Lynn B. Morreale	Registration No. 32,842
Dale M. Heist	Registration No. 28,425	Mark DeLuca	Registration No. 33,229
John W. Caldwell	Registration No. 28,937	Joseph Lucci	Registration No. 33,307
Gary H. Levin	Registration No. 28,734	Michael P. Dunnam	Registration No. 32,611
Steven J. Rocci	Registration No. 30,489	Michael D. Stein	Registration No. 34,734
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Terence P. Strobaugh	Registration No. 25,460	Jane Smith Inglese	Registration No. P48,444
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Telephone No.: (215) 568-3100
Facsimile No.: (215) 568-3439

A Statement under 37 C.F.R. §3.73(b) and copies of relevant documents accompany this Power of Attorney.

CHIRON CORPORATION

Date: 14 January 2001

By:

Name: **Alisa A. Harbin**

Title: **Vice President and Associate Chief
Patent Counsel**

